



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Handling of Item/Instruments/Accessories Dropped On Floor During Aseptic Operations

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 2

1.0 OBJECTIVE:

To lay down a Procedure for Handling of Item / Instruments /Accessories Dropped on Floor during Aseptic Operations.

2.0 SCOPE:

This SOP is applicable for Handling of Item / Instruments /Accessories Dropped on Floor during Aseptic Operations in Clean Room of production department.

3.0 RESPONSIBILITY:

Officer / Executive Production / Engineering

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BPCR Batch Production & Control Record
IPA Isopropyl Alcohol
Ltd. Limited
QA Quality Assurance
SOP Standard Operating Procedure

6.0 PROCEDURE:

6.1 During aseptic operation do not pick any dropped item from Floor e.g. Forceps, Vials, Stoppers, Seals, HDPE Vials, Nozzle, cap & Sterile Garments etc.

6.2 The dropped item shall be picked at end of working session.

6.3 Disinfect hands up to elbow with 70% IPA (0.2 micron filtered) before picking up the dropped item.

6.4 Pick up stuck Vials / Plugs / Seals/HDPE Vials/ Nozzle/ cap with Sterile Forceps and reject them.

6.5 Empty the Reject Vials at reject station by picking up with sterile forceps, collect the Reject Vials / Plugs / Seals in SS Container having status label of rejection & record in BPCR.

6.6 Discard the collected reject.

6.7 Disinfect hands up to elbow with 70% IPA

6.8 Tools used during maintenance if dropped shall be disinfect by wiping with 70% IPA & after completion of activity outer hand gloves shall be changed.

7.0 ANNEXURE:

Not Applicable

ENCLOSURE: SOP Training Record



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8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production
- Master Copy Quality Assurance

9.0 REFERENCE :

In House

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By